DMB

Display Date 7-17-00
Publication Date 7-18-00
Certifier SNREESE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2152]

3525 JUL 17 A5:35

Guidance for Industry and FDA Reviewers on Medical Device Use—Safety: Incorporating Human Factors Engineering into Risk Management; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled ''Medical Device Use—Safety: Incorporating Human Factors Engineering into Risk Management.'' This guidance describes how to incorporate human factors techniques and theory into risk management during medical device design and development. The guidance is intended to assist reviewers of premarket device submissions, design control documentation, and manufacturers that develop devices. The guidance is necessary to decrease problems with the use of medical devices that impact safety and effectiveness, and help ensure safer and more effective devices.

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Medical Device Use—Safety: Incorporating Human Factors Engineering into Risk Management'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments on ''Medical Device Use—Safety: Incorporating Human Factors Engineering into Risk Management'' to the contact person listed

NAD 2

below. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Ron D. Kaye, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850 301–443–2436.

SUPPLEMENTARY INFORMATION:

I. Background

The guidance is intended to provide a suggested approach for integrating human factors within risk management for medical device design and development. It also contains an introduction to both risk management and human factors and a discussion of how they are linked. The focus is on reducing hazards related specifically to the use of medical devices. Human factors techniques are discussed within the context of applying risk management. The guidance also suggests how human factors-risk management efforts should be documented and included in premarket submissions. This guidance document was published for public comment on August 3, 1999, as a draft guidance entitled ''Device Use Safety: Incorporating Human Factors in Risk Management.'' The document has been modified from the original draft version to address public comments. There were changes made in the document for the purposes of clarity, but there were no major substantive changes.

II. Significance of Guidance

This guidance document represents the agency's current thinking on the application of human factors to new medical device design and development to help ensure that intended users can use a device safely and effectively. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

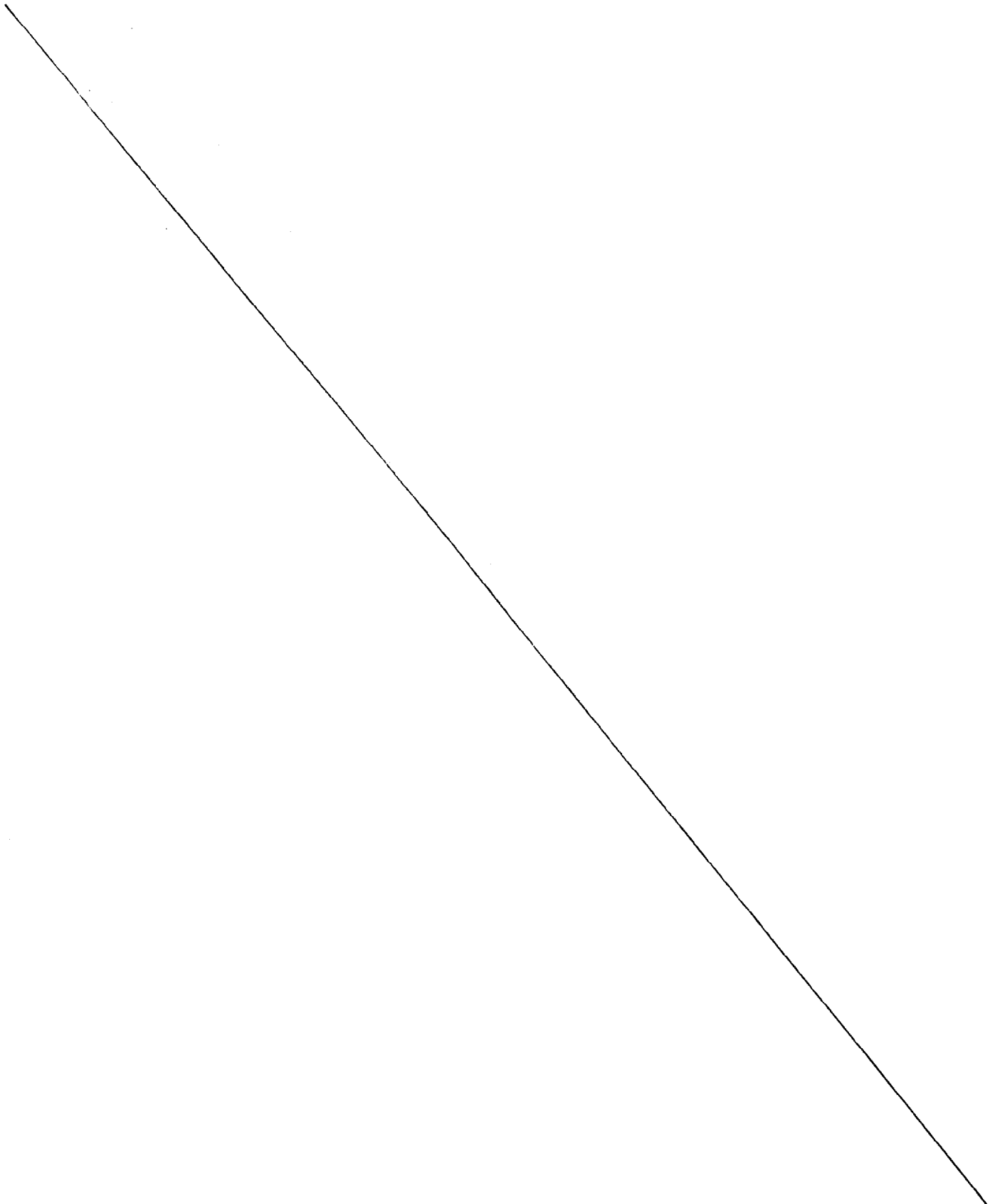
In order to receive ''Medical Device Use—Safety: Incorporating Human Factors Engineering into Risk Management'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touchtone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1497) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes ''Medical Device Use—Safety: Incorporating Human Factors Engineering into Risk Management,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Medical Device Use—Safety: Incorporating Human Factors Engineering into Risk Management'' is also available at http://www.fda.gov/cdrh/HumanFactors.html.

IV. Comments

Interested persons may, at any time, submit written comments on the guidance to the contact person (address above). Such comments will be considered when determining whether to amend

the current guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets



in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 7/5/00
July 5, 2000

Linda S. Kahan,
Deputy Director for Regulations Policy,
Center for Devices and Radiological Health.

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

BILLING CODE 4160–01–F